

INFORMED CONSENT DOCUMENT

Project Title: Functional Imaging Reserve in NeuroHIV (FIRN)

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form, you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are 18-80 years old and either HIV+ or HIV-.

The purpose of this research study is to look at the brain's efficiency and ability to make up for deficits in the front of the brain to see if people living with HIV (PLWH) are still able to perform well on various cognitive tasks even though there are still other underlying processes at work, like inflammation, that affect the brain in a negative way. Results of this study may provide insight into the pathophysiology of disease and may reveal arenas for future possible interventions in PLWH who have impaired neuropsychological performance.

WHAT WILL HAPPEN DURING THIS STUDY?

For all participants, you must be willing to wear a mask at all times when on the medical school campus.

In order to determine your eligibility to continue on the study, you will have a screening evaluation, which includes:

1. Urine pregnancy tests (done on the day of the scan, only for females with no documented history of sterilization, menopause, etc.)
2. A urine drug screening test for cocaine, amphetamines, methamphetamine, barbiturates,

benzodiazepines, marijuana, opiates, PCP, methadone, and tricyclic antidepressants, such as amitriptyline or nortriptyline. A positive result will not necessarily exclude you from the study.

3. Oral HIV test (for negative controls only). This test is done by rubbing a swab over your gumline once.

4. The Neuroimaging Screening Form, which asks questions about your feelings about being inside a closed space like the MRI scanner, questions about history of head injuries, and questions about any metal that subjects may have implanted in your body or any metal piercings that cannot be removed.

5. A Locator Form with your basic contact information, as well as additional names of people who might also be able to contact you should you be lost to follow up. When asking for your zip code on this form, we will use it not only to contact you, but also to determine the median income for the area in which you live.

6. Scanning Cover Sheet – You will be asked questions about your demographics and other basic information, such as age, race, gender, handedness, years of education, first language, height/weight, date of HIV diagnosis (and date started medications if applicable), as well as information about drug, alcohol, tobacco and caffeine use. When asking for your zip code on this form, we will use it not only to contact you, but also to determine the median income for the area in which you live.

7. You will also be asked to sign a Release of Information form so we can obtain your medical records, including but not limited to medical, hospitalization, HIV, STD, substance use/abuse/dependence and mental health records from your doctors, results from prior blood, diagnostic, imaging and laboratory tests and other information obtained from interviews or questionnaires related to your medical care. We may also review the records of any Washington University research study in which you participate. This will allow us to better determine your eligibility to continue on study, insure and improve your safety, and decrease your burden if the results of tests done in one research study could be used as data for another instead of asking you to unnecessarily repeat a procedure.

8. We will review your medical history and records related to any HIV/AIDS-related outpatient visits or any significant medical history, inpatient hospitalizations, blood/diagnostic/laboratory/imaging tests (such as CD4 count, viral load, nadir CD4 count, duration of infection, STD history, and any other HIV- or inflammatory-related labs deemed necessary, any abnormal/exclusionary imaging results, etc.), substance use/abuse/dependence, and mental health treatment. Additional information may also be obtained from clinical interviews or questionnaires found in your records related to your medical care. We may also review your research records from other WUSM studies (to see if previous results indicate any exclusionary criteria or provide any results that we could use as data for this study so as to not have you repeat procedures and decreasing your burden whenever possible). These records will only be accessed as long as necessary to acquire study data.

If, on the basis of these tests and at the PI's discretion, you are eligible to continue in the study, you will be asked to complete the following study procedures. The Screening Evaluation and Baseline Assessments can be completed on the same or separate days.

BASELINE ASSESSMENTS:

1. **Neuropsychological (Memory) Tests** -- These are exercises that are related to memory, how fast you do things with your hands, and how you pay attention to tasks. There are a number of different tasks; some are timed and some are not. These will take approximately 1-1½ hours to complete.
2. **Questionnaires** regarding your mood, ability to care for yourself, as well as your drug and alcohol history. These will take approximately ½-1 hour to complete, and you may skip any questions that make you feel uncomfortable.
3. **Neuromedical and physical examination** -- A doctor will examine the nerves in your face, as well as test your reaction to touch and will test the reflexes in your arms and legs. We will check your waist circumference, height, weight, take your vital signs (blood pressure, heart rate, respiration, etc.), and also perform a regular physical. This will take approximately 20 minutes.
4. **Fasting labs:** We will ask you to fast (not have anything to eat or drink other than water) overnight (approximately 10-12 hours) and then draw some of your blood to look at the amount of fat and sugar in your body, as well as markers of inflammation and insulin resistance. The blood draw will be equivalent to approximately 9 tablespoons, including blood samples taken to determine if you are a carrier of the *Apolipoprotein E (ApoE) ε4* allele. This is a genetic test to help further our understanding of HIV-related dementia (memory loss and thinking problems) and other neurodegenerative disorders (neurodegeneration refers to the progressive loss of structure or function of nerve cells). Some versions of this allele may increase a person's risk of developing Alzheimer's disease in their lifetime. This *ApoE* test is for research purposes only and its result will not be reported to you or your physician. If, during your first visit, we are unable to acquire the full amount of blood necessary to perform these laboratory tests, you may be invited back to try again. You are under no pressure to agree to return, however, if you do, you will be remunerated again for letting us attempt another blood draw at a subsequent visit.
5. **Stool Sample:** You will be provided a stool collection kit to collect a stool sample. Preferably this sample will be from your first morning stool, but any stool sample not more than 24 hours old will be OK. When you bring in your sample, you will also be given a questionnaire to fill out about your recent diet.
6. **Magnetic Resonance Imaging (MRI)** -- The MRI scanner is a powerful magnet that uses simple radio waves to take pictures of your brain. You will be positioned on your back on the scanner bed and made to feel as comfortable as possible. The scanner bed will be moved inside a large tube so that your head and your chest are inside, but you will be able to see out into the room by your feet. During the scan, you will hear loud, rhythmic knocking sounds. Your ears will be covered to keep the noise at a minimum. There is a speaker and a microphone in the scanner so that you can talk to the MRI technician if there is something you need. Once the scan starts, you will need to lie still since moving around will interfere with taking pictures of your brain. You will be able to end the scan at any time if you feel uncomfortable. You may be asked to do a task while in the scanner. The MRI will take approximately 1 hour to complete. The images we acquire for this study are for specific research purposes and are not being used to evaluate your health or find medical abnormalities. These images will not regularly be reviewed by a radiology physician to diagnose existing abnormalities. The scan will take approximately 60-90 minutes.

7. Optional Lumbar Puncture – Sometime within approximately 6 months after you complete the memory testing and MRI, you will be asked to return for a lumbar puncture (LP). We will ask you to fast (not have anything to eat or drink other than water) overnight (approximately 10-12 hours) before you come in for the LP. This procedure lasts approximately 45 minutes and involves putting a small needle in your lower back through the space between bones below where the spinal cord ends to collect some cerebral spinal fluid (CSF) (up to 25 cc's or 1-2 tablespoons). Spinal fluid is the fluid that moves around the brain and spinal cord. You will have your vitals (blood pressure & heart rate) taken before and after the procedure, and you will be given a numbing medication before the LP is done in order to reduce any pain or pressure you may feel during the procedure. If we are unable to acquire the full amount of CSF necessary, you may be invited back to try again. You are under no pressure to agree to return, however, if you do, you will be remunerated a second time for letting us attempt another LP at a subsequent visit.

***Of note, in order to minimize participants' potential exposure to COVID-19, any procedures that can be done remotely (such as neuropsychological assessments and questionnaires) will be done over the phone, via Zoom and/or Redcap whenever possible. When you're on campus, though, you will always be required to wear a mask. ***

RISKS ASSOCIATED WITH THE LUMBAR PUNCTURE

Likely: Pain at the site of needle insertion.

Less Likely: Headache.

Rare: Lowered blood pressure, infection, leaking of spinal fluid after the procedure, nerve injury, and bleeding at the needle insertion site. Additionally, an allergic reaction to the antiseptic (e.g. iodine) or the numbing medicine (lidocaine) used during the spinal tap could include itching, hives, swelling, shortness of breath, difficulty breathing, changes in blood pressure and heart rhythm, loss of consciousness or, in a rare case, death

I agree to the lumbar puncture as described above.

<u> </u> Yes	<u> </u> No
Initials	Initials

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood, cerebrospinal fluid (CSF), and other data (stool, MRI, neuropsychological assessments & questionnaires) from you. We would like to use this blood, CSF, and other data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding HIV or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use blood, CSF, and other data, you give up any property rights you may have in the blood, CSF, and other data.

Some of this future research may involve genetic testing. Genetics is a discipline of biology that studies how living things receive common traits from previous generations.

We will share your blood, CSF, and other data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information. The shared information will not include your name but may be linked by a global unique identifier (GUID) number.

If you change your mind and do not want us to store and use your blood, CSF, and other data for future research you should contact the research team member identified at the top of this document. The blood, CSF, and other data will no longer be used for research purposes. However, if some research with your blood, CSF, and other data has already been completed, the information from that research may still be used. Also, if the blood, CSF, and other data has been shared with other researchers it might not be possible to withdraw the blood, CSF, and other data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 400 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 6-7 hours total, split over 2-3 days (approximately 4 hours for neuropsych and questionnaires, 1½ -2 hours for MRI and fasting labs, plus 1 hour LP). Depending on scheduling availability and your preference, we will do our best to condense or expand the MRI and neuropsych into as many or few days as is comfortable for you. The LP, however, must always be done on a separate day from the rest of the procedures, approximately 1 week to 6 months later.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

RISK OF THE SCREENING, NEUROPSYCHOLOGICAL (MEMORY) TESTS, & QUESTIONNAIRES

Likely: None

Less Likely:

- You may feel embarrassed or uncomfortable answering some of the questions.

- You may experience fatigue or embarrassment from the exercises of memory, movement, and attention.

You may discuss any question that concerns you with the coordinator, and you may choose not to answer any question that makes you feel uncomfortable.

Rare: None

RISKS of MRI

Common risks:

- discomfort inside the MRI scanner if you do not like to be in closed spaces (“claustrophobia”)
- muscle stiffness from lying still
- feeling warm
- feeling a twitching sensation briefly during the scan.

Rare risks:

- a loud hammering noise which has caused hearing loss in a small number of patients.
 - To minimize this risk you will be given earplugs.
- temporary sensation of flashing lights while in the MRI scanner
- burns that could be serious
 - To minimize this risk we will have you change out of your clothing and into clothing that we provide.

During the procedure, you will be able to talk with the MRI staff through a speaker system. If you experience any of these symptoms and do not wish to continue, you can ask that the scan be stopped immediately.

Devices

If you have a device such as a pacemaker, bone hardware, or device placed in your uterus there may be additional risks. We will review what device you have and inform you of these risks. In general, these risks could be:

- heating or movement of the device
- device malfunction
- damage to the tissue that surrounds the device.

Rare:

- Occasionally, some people may experience a short period of dizziness or feel faint after being in the scanner.

There is a rare possibility that a serious abnormality may be discovered by the technician during the MRI picture of your brain. A radiologist will review MRI scans for clinical findings. If there is an incidental observation on the MRI which may be clinically significant, the Principal Investigator (PI) will be contacted. If indicated, with your permission, the PI or his/her designee will contact your doctor with this information. If you request it, a copy of your brain MRI scan can be shared with your doctors. In this event, you will be referred to your primary care physician and/or the WUSM Neurology Clinic for clinical follow up and treatment as appropriate. While we will never put your consent form or study data in your medical records, once we notify your physician and make relevant brain MRI's and test results available to him/her for clinical follow up, that information may become part of your health care

records.

RISKS ASSOCIATED WITH BLOOD DRAW

Likely: Pain, stinging, bruising and bleeding at the site of needle insertion.

Less Likely: None

Rare: Infection at the site or blood clot.

Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Testing for Reportable Diseases (Negative Controls Only)

If you decide to participate in this study, we will test you for HIV. The results of this test could indicate that you have this condition. If that happens, we will refer you to a doctor who specializes in treating your condition. We will make every effort to keep your personal information confidential. However, we are required by law to report certain positive tests to the state of Missouri and/or local agencies. The test results could also be reported to the Centers for Disease Control. You may be contacted by these agencies for more information. Becoming aware of a new diagnosis could have serious health, personal and/or social consequences. For more information about the risks of this testing, please talk to your study doctor.

Genetics

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the knowledge gained may lead to better therapy options for PLWH.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you; it should take between approximately 2-4 weeks for you to receive your check. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

Below is a list of the payment amount for the completion of each study procedure:

Total Compensation for all assessments = \$275

- MRI = \$75
- Neuropsychological assessments = \$60
- Questionnaires = \$15
- Laboratory evaluations = \$25
- Stool sample and dietary survey = \$25
- Lumbar Puncture = \$75
- *Optional/As Needed (not included in Total Compensation):* Online COVID-19 Survey Questionnaire = \$30

If you complete all of the study procedures you will be paid a total of \$305.

Remuneration for the neuropsych assessments will be prorated, based on the per cent of assessments that you complete; for example, if you only complete half (50%) of the assessments, you will only receive half of the payment (\$30.00).

If you do not complete the MRI, laboratory evaluations, stool sample with dietary log, or lumbar puncture, you will not be paid. Remuneration for these procedures will not be prorated.

WHO IS FUNDING THIS STUDY?

The National Institute of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314/747-8423 and/or the Human Research Protection Office at 800/438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- NIH
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives to complete Hospital or University responsibilities
- A radiologist will review MRI scans for clinical findings. If there is an incidental observation on the MRI which may be clinically significant, the Principal Investigator (PI) will be contacted. If indicated, with your permission, the PI or his/her designee will contact your doctor with this information. If you request it, a copy of your brain MRI scan can be shared with your doctors. This scan may then become part of your healthcare records.
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will keep all information in a locked area. The information you give us will be given a code number. A master list linking the code number and your identity will be kept separate from the research data. Only the Principal Investigator and people helping him will be able to see the list, and all staff involved with this project have been thoroughly trained in the protection of research participants. We will protect your information, but there is a chance somebody might see it. We will protect your genetic information by using a code which cannot be traced back to you. This code

will be assigned once we've collected all of the information we need for our study from your medical record. This may take up to one month. We will not sequence your DNA until your identifiers have been stripped.

Your MRI and PET scans will be labeled with a code number. It will be stored at Washington University using the code number, along with the date of the scan. Using the code number, it will be linked to the other information about you that is collected in this study.

The details in your medical record will be stripped of identifiers (name, date of birth, address, social security number, medical record numbers) and entered into a database associated with a participant code number. Dates of procedures will be recorded in the database. Only qualified study staff within the Washington University School of Medicine, who agree to keep your data secure, will have access to identifiers when needed. This database will be updated on a periodic basis from your medical records in the following years in order to update your information on medications, surgeries, cognitive testing, disease activity, and disease history. We will store your medical information indefinitely. In the event that the medical record does not contain this information, you may be contacted by study staff to obtain that information directly from you.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
 - your insurance payment or enrollment in any health plans.
 - any benefits to which you are entitled.
- However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
- To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.
 - **If you revoke your authorization:**
 - The research team may only use and share information already collected for the study.
 - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
 - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you, such as

- appointment scheduling/reminders containing PHI
- Links to complete study assessments on Redcap
- copies of current/updated consent forms and other information for this study
- consent forms and information for other studies you have requested.

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer, you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.

- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

 Yes No
Initials Initials

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because:

- you have certain medical conditions like seizures, use of illegal drugs, or pregnancy
- in our judgment it would not be safe for you to continue
- the funding for the research study has ended

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Regina Thompson at 314/747-8421 or John Doyle at 314/747-1072. If you experience a research-related injury, please contact: Elizabeth Westerhaus at 314/747-1125.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 05/11/22.

(Signature of Participant)

(Date)

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)

(Name of Person who Obtained Consent - printed)